RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Consent Form Revisions – July 13, 2020 (Effective 7/27/2020)

Version 12.0 (Status Review) – June 14, 2019
Version 11.0 (Continuing) – July 30, 2018
Version 10.0 (Continuing) – July 30, 2017
Version 9.0 (Continuing) – July 30, 2016
Version 8.2 (Continuing) – July 30, 2015
Consent Form Revisions – February 24, 2015
Version 8.1 (Continuing) – July 30, 2014
Version 8.0 (Continuing) – July 30, 2013
Version 7.0 (Continuing) – July 30, 2012
Version 6.0 (Continuing) – July 30, 2011
Version 6.0 (Continuing) – July 30, 2010
Version 5.1 (Continuing) – July 30, 2009
Version 5.0 (Continuing) – July 30, 2008
Version 4.1 (Continuing) – July 30, 2007
Version 4.0 (Amendment) – April 26, 2007 (Effective 6/11/07)
Version 3.0 (Continuing) – July 30, 2006
Version 2.5 (Continuing) – July 30, 2005
Version 2.4 (Amendment) – May 20, 2005
Version 2.3 (Amendment) – May 1, 2005
Version 2.2 (Continuing) – July 30, 2004
Version 2.1 (Amendment) – January 28, 2004
Version 2.0 (Continuing) – October 1, 2003
Version 1.0 – July 2002

Description of Revision	Document/Section(s) Affected	Effective Date
Section 5: Paragraph 2 [insert <u>center name</u> ~~location~~ here] Section 5: Added "This research is covered by a Certificate of Confidentiality from the Health Resources and Services Administration (HRSA)." to paragraph 5. Section 6: Cost and Reimbursement language expanded	**Consent Forms:** Donor Adult/Parent Consent Form; Donor Match Algorithm Consent Form; Recipient Marrow Toxic Injury Adult/Parent Consent Form; Recipient Adult/Parent Consent Form; Recipient Secondary Primary Malignancy Adult/Parent Consent Form.	7/27/20
Replaced "brother or sister" with "family member" through the assent forms.	**Assent Forms:** Minor Related Donor Assent Form 7-11 and 12-17	7/27/20
Updated formatting of the page number in the footer)	**Assent Forms:** Minor Recipient Assent (12-17) and Minor Marrow Toxic Injury Assent Form (12-17)	7/27/20
Re-formatting of consent forms	All consent forms	6/14/19
Merged separate Adult and Parent/Legal Guardian consent forms into one Adult Parent/Legal Guardian consent form	**Consent Forms:** Adult Research Consent Form and Parent/Legal Guardian Permission Form Allogeneic or Autologous Recipient; Adult Research Consent Form and Parent/Legal Guardian Permission Form Allogeneic Donor; Adult Research Consent Form and Parent/Legal Guardian Permission Form Marrow Toxic Injury Patient	6/14/19

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

2nd paragraph, 2nd sentence: "…name and the alphanumeric code."	**Protocol:** section 10.1	6/14/19
2nd paragraph, 1st sentence: "…only with an alphanumeric code…"	**Protocol:** section 10.1	6/14/19
1st paragraph, 3rd sentence: "~~If the subject's sample has already been given to an investigator at the time he/she asked to withdraw from the Research Repository, the investigator will be instructed to remove the subject's sample from their study set.~~ Any unused sample will be destroyed."	**Protocol:** section 9.0	6/14/19
1st paragraph, 1st sentence: "…samples obtained from the ~~NMDP~~ Research Sample Repository…"	**Protocol:** 10.3	6/14/19
Added 5th paragraph: "Additionally, NMDP and MCW maintain appropriate technical and organizational measures for the adequate protection of the security and privacy of its systems and data. These protections comply with the United States National Institute of Standards and Technology, Security Controls for Federal Information Systems (NIST 800-53), and all other applicable security and data privacy requirements. These safeguards are audited annually by a qualified independent auditor; results are reported to CIBMTR management for timely resolution."	**Protocol:** section10.1	6/14/19
Added 4th paragraph: "All research staff at the CIBMTR and the NMDP maintain up-to-date training in protection of human subjects. This training is received through the Collaborative IRB Training Initiative (CITI) program. This is a web-based training program offered through the Biomedical Research Alliance of New York (BRANY)."	**Protocol:** section 10.1	6/14/19
Added 3rd paragraph: "Access to all information in the Research Sample Repository is tightly controlled with passwords and logins at multiple levels. Access to the Research Sample Repository is limited to those employees who have specific job responsibilities related to the repository."	**Protocol:** section 10.1	6/14/19
1st bullet point: "~~All sample data is stripped of identifying sequences, e.g. Y chromosome, mitochondrial DNA, or other unique sequences, dates and detailed demographic data prior to submission to dbGAP.~~"	**Protocol:** section 8.6	6/14/19
1st paragraph, 1st bullet point: "…NMDP/CIBMTR ~~r~~Research ~~d~~Database, subject to provisions of the ~~r~~Research ~~d~~Database protocol…"	**Protocol:** section 8.4	6/14/19
Removed section 4.1.2 Related Donor Transplants or Cellular Therapies	**Protocol:** section 4.1.2	6/14/19
7th bullet point: "In cases where the center ~~has designated~~ is relying on the NMDP IRB for this process~~ their IRB of record for the Research Repository protocol, and an IRB Authorization Agreement is in place,~~ the center…"	**Protocol:** section 3.1	6/14/19
6th bullet point, 1st sentence: "…review period if the center has not transitioned the protocol to the 2018 Common Rule requirements. If the center transitioned the protocol to the 2018 Common Rule requirements, then the above process is only followed when there are amendments to the protocol or consent forms."	**Protocol:** section 3.1	6/14/19
4th bullet point: "…submitted to the NMDP IRB office~~ at the~~	**Protocol:** section 3.1	6/14/19

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

~~NMDP."~~		
3rd bullet point: "…the local IRB ~~need to~~ must be reviewed…"	**Protocol:** section 3.1	6/14/19
1st bullet point: "The ~~NMDP's template~~ protocol…"	**Protocol:** section 3.1	6/14/19
Removed 1st sentence: "~~The process for local and NMDP IRB approval are as follows.~~"	**Protocol:** section 3.1	6/14/19
Added 3rd paragraph: "International centers must follow their own national regulations and provide assurance to the CIBMTR that national regulations are being followed."	**Protocol:** section 3.0	6/14/19
2nd paragraph: "~~Local IRB review and approval is necessary except in the case of centers that designate the NMDP IRB as their IRB. Centers must use the protocol and consent forms provided by the NMDP and submit them to their designated IRBs for review and approval.~~ This protocol and its associated consent forms are provided to centers on the CIBMTR website, www.cibmtr.org."	**Protocol:** section 3.0	6/14/19
1st paragraph, added 2nd sentence: "The center may obtain IRB approval either through their local IRB or delegate review to the NMDP IRB through an IRB Authorization Agreement."	**Protocol:** section 3.0	6/14/19
1st paragraph, 1st sentence: "…centers must ~~have~~ obtain IRB-approv~~ed~~al for the protocol…"	**Protocol:** section 3.0	6/14/19
1st bullet point added: "…as set forth in 45 CRF 46.408."	**Protocol:** section 2.5.1	6/14/19
Added 1st paragraph: "The Research Sample Repository included pediatric patients and related donors. The procedural risk involved in this protocol meets the definition of minimal risk set forth in 45 CFR 46.106 (i) "*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."* Participation on this protocol requires a routine blood draw."	**Protocol:** section 2.5.1	6/14/19
Added 2nd paragraph: "Non-U.S. centers contributing samples to the Research Sample Repository will provide written assurance that the submission of samples has on-going oversight by their local Ethics Review Board/Medical Ethics Committee and all regulations are followed."	**Protocol:** section 2.5	6/14/19
1st paragraph, added 3rd and 4th sentence: "To confirm that participants have given consent to participate in the Research Sample Repository, the first form submitted to the Research Database on a participant includes confirmation that the participant signed the informed consent document. Institutional IRB policies must be followed regarding re-consent of minor patients when those patients reach the age of majority."	**Protocol:** section 2.5	6/14/19
1st paragraph, 2nd sentence: "~~Documentation of assent and of parent legal guardian permission of minor participants, and consent for adult participants, must be maintained at the center where the participant or their parent or legal guardian provided consent to participate.~~ The center where consent is obtained is responsible for maintaining the written consent form and documentation of the mirror assent decision."	**Protocol:** section 2.5	6/14/19

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

1st paragraph, added new 1st sentence: "In the event of a radiation exposure accident, the NMDP has a radiation injury treatment network, whose purpose is to collect data to understand the outcomes of patients treated under these circumstances."	**Protocol:** section 2.4	6/14/19
2nd paragraph: "All donors registered on the NMDP Registry, regardless of whether they have been requested to donate a product for a patient, are eligible to participate in the Research Sample Repository. ~~Registered volunteer donors are eligible to participate in the NMDP Research Sample Repository if selected for further tissue type characterization in research projects designed to enhance the NMDP search (match) algorithm. Search algorithm enhancement research will entail potential donor match identification, verification of donor tissue type (including rare tissue types) and analyses to further characterize factors that impact histocompatibility. A tissue type is considered rare if it has been found in less than one in a million donors on the NMDP registry. Donors with rare tissue types will be targeted based on HLA typing results reported to the NMDP.~~	**Protocol:** section 2.1	6/14/19
1st paragraph, added last sentence: "This includes adults with and without decision making capacity and children."	**Protocol:** section 2.1 & 2.3	6/14/19
3rd paragraph, 1st bullet point: "Investigate molecular explanations for histocompatibility or clinical outcome revealed through analysis of genomic, epigenetic, or other biomolecular data; ~~Improve the understanding of tissue matching for HSC or cellular therapy donor and recipients~~	**Protocol:** section 1.3	6/14/19
3rd paragraph, 1st sentence: "…of studies that ~~the NMDP allows~~ the samples ~~to~~ may be used…"	**Protocol:** section 1.3	6/14/19
2nd paragraph, 1st sentence: "The ~~NMDP~~ Research Sample…"	**Protocol:** section 1.3	6/14/19
1st paragraph, 3rd sentence: "…donated or received a~~n allogeneic or autologous~~ HSC transplant…"	**Protocol:** section 1.3	6/14/19
1st paragraph, 1st sentence: "…NMDP established the ~~NMDP~~ Research Sample Repository which is currently located at the NMDP ~~Repository~~ Biorepository services…"	**Protocol:** section 1.3	6/14/19
Section 1.2: "The International Blood Marrow Transplant Registry (IBMTR), located with the Department of Medicine of the Medical College of Wisconsin, was established in 1972 to monitor and study outcomes of bone marrow transplants. In 2004 the NMDP and IBMTR established the Center of Blood and Marrow Transplant Research (CIBMTR). The CIBMTR is a research affiliation between the NMDP and the Medical College of Wisconsin. The CIBMTR has both a Minneapolis campus located within the NMDP offices and a Milwaukee campus at the Medical College of Wisconsin. The NMDP Research Program is accomplished through the CIBMTR."	**Protocol:** section 1.2	6/14/19
Added new section 1.2: "Center for International Blood and Marrow Transplant Research®"	**Protocol:** section 1.2	6/14/19
Added second paragraph: "In addition, the Federal contract also recognized that the NMDP could play a critical role in responding to contingency events; primarily radiation and	**Protocol:** section 1.1	6/14/19

chemical exposures occurring either accidentally or resulting from military or terrorist actions that cause a marrow toxic injury."		
1st paragraph, 2nd sentence: "…matching related donor. As part of the Federal contract the NMDP was required to collect outcomes data and research samples on patients who received a product through NMDP."	**Protocol:** section 1.1	6/14/19
Changes references from "NMDP IRB Chair" to "Research Repository Principal Investigator"	**Protocol:** Throughout	6/14/19
Changes references from "NMDP Research Sample Repository" to "Research Sample Repository"	**Protocol:** Throughout	6/14/19
Changed references from "HSC" to "HC"	**Protocol:** Throughout	6/14/19
Changed references from "Recipient" to "Patient"	**Protocol:** Throughout	6/14/19
Section 10.1 heading: "Coded Sample Inventory ~~and~~, Links to Personal Identifiers and Staff Training and Access"	**Protocol:** section 10.1	6/14/19
Section 6 heading: "Duration of Sample Storage at the ~~NMDP~~ Research Sample Repository"	**Protocol:** section 6	6/14/19
Added Section 3 Sub-title: 3.1 IRB Approval Process	**Protocol:** section 3.0	6/14/19
Updated section header 4.1.3 Autologous Transplants or Cellular Therapies to 4.1.2	**Protocol:** section 4.1.3	6/14/19
Section 4.1.1 heading: "Unrelated and Related Donor Transplant or Cellular Therapies"	**Protocol:** section 4.1.1	6/14/19
Section 2.4 heading: "~~Individuals~~ Patients With Marrow Toxic Injury Eligibility Criteria"	**Protocol:** section 2.4	6/14/19
Section 2.3 heading: "Hematopoietic ~~Stem~~ Cell or Other Cellular Therapy Recipients Eligibility Criteria"	**Protocol:** section 2.3	6/14/19
Section 2.2 heading: "Cord Blood Units Eligibility Criteria"	**Protocol:** section 2.2	6/14/19
Section 2.1 heading: "Hematopoietic ~~Stem~~ Cell or Other Cellular Therapy Recipients Eligibility Criteria"	**Protocol:** section 2.1	6/14/19
Section 2 heading: "Eligibility to Participate in the ~~NMDP~~ Research Sample Repository"	**Protocol:** section 2	6/14/19
Section 1.3 heading: "Establishment and Purpose of the ~~NMDP~~ Research Sample Repository"	**Protocol:** section 1.3	6/14/19
Added new section 1.2: "Center for International Blood and Marrow Transplant Research®"	**Protocol:** section 1.2	6/14/19
Section 1.2 renamed section 1.3	**Protocol:** section 1.2	6/14/19
Updated Table of Contents to match body of the protocol.	**Protocol:** Page 2 Table of Contents	6/14/19
Changed version # to 12.0 and version date to **TBD**	**Protocol:** Title page **Record of Revisions**: Title Page	6/14/19
Added Title page: "Stephen Spellman, M.S. CIBMTR Assistant Scientific Director Director, Immunobiology Research"	**Protocol:** Title page	6/14/19
Removed "Allogeneic" and "Stem" from title of protocol	**Protocol:** Title Page **Record of Revisions**: Title Page	6/14/19
Changed footer: GRID (if applicable) line added	**Donor Consent Form:** Footer	4/29/2019
New Assent Form: Minor Recipient Assent Form (7 to 11 years of age) Secondary Primary Malignancy		04/24/2019
New Assent Form: Minor Recipient Assent Form (12 to 17 years of age) Secondary Primary Malignancy		04/24/2019
New Consent Form: Adult Research Consent Form and		04/24/2019

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Parent /Legal Guardian Permission Form Allogeneic or Autologous Recipient Secondary Primary Malignancy		
Changed title: "Minor ~~Allogeneic~~ Recipient Assent Form"	**Assent Forms:** Recipient Assent 7-11; Recipient Assent 12-17	07/30/2018
3rd paragraph, added last sentence: "You may be asked to give another blood sample in the future if something happens like your disease comes back, but you don't have to give any future blood samples if you don't want to."	**Assent Forms:** Recipient Assent 12-17	07/30/2018
2nd paragraph, added last sentence: "You might be asked to give another blood sample in the future, but you don't have to give another one if you don't want to."	**Assent Forms:** Recipient Assent 7-11	07/30/2018
Changed title: "Minor ~~Allogeneic~~ Recipient Parent/Legal Guardian Research Permission Form"	**Recipient Consent Forms (Title):** Minor Recipient Parent/Legal Guardian	07/30/2018
1st paragraph, added last two sentences: "You may also be asked to contribute a blood sample in the future after a specific clinical event (disease relapse, development of a new cancer or other event). Your participation in this protocol does not obligate you to provide future samples."	**Recipient Consent Forms (Section II):** Adult Recipient; Minor Recipient Parent/Legal Guardian;	07/30/2018
After 1st paragraph, added: "This research is covered by a Certificate of Confidentiality from the Federal Government. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Health Resources and Services Administration (HRSA) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your	**Recipient Consent Forms (Section IV):** Adult Recipient; Minor Recipient Parent/Legal Guardian; **Marrow Toxic Injury Consent Forms (Section IV):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian **Donor Consent Forms (Section IV)** Adult Allogeneic Donor; Minor Related Donor Parent/Legal Guardian; Adult Registered Donor for Match Algorithm Enhancement;	07/30/2018

involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it."		
1st paragraph: "The Center for International Blood and Marrow Transplant Research (CIBMTR), ~~the~~ a research ~~program~~ collaboration of the National Marrow Donor Program (NMDP)/Be The Match and the Medical College of Wisconsin, invites you to take part in the Research…"	**Recipient Consent Forms (Section I):** Adult Recipient; Minor Recipient Parent/Legal Guardian; **Marrow Toxic Injury Consent Forms (Section I):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian **Donor Consent Forms (Section I)** Adult Allogeneic Donor; Minor Related Donor Parent/Legal Guardian; Adult Registered Donor for Match Algorithm Enhancement;	07/30/2018
Added entire section 10.2: "Certificate of Confidentiality"	**Protocol:** Section 10.2	07/30/2018
Added entire section 4.2: "Post-transplant or Cellular Therapy Collection of Recipient Blood Samples"	**Protocol:** Section 4.2	07/30/2018
Added entire section 4.1.3: "Autologous Transplants or Cellular Therapies"	**Protocol:** Section 4.1.3	07/30/2018
1st paragraph, 1st sentence: "Recipient pre-transplant or cellular therapy samples are collected prior to the…"	**Protocol:** Section 4.1.2	07/30/2018
1st paragraph, 1st sentence: "Recipient pre-transplant or cellular therapy samples are collected prior to the…"	**Protocol:** Section 4.1.1	07/30/2018
Section 4.1 heading: "Pre-Transplant or Cellular Therapy Collection of Donor and Recipient Blood Samples"	**Protocol:** Section 4.1	07/30/2018
1st paragraph: "All U.S. recipients of allogeneic or autologous HSC transplants or cellular therapies…"	**Protocol:** Section 2.3	07/30/2018
Section 2.3 heading: "Hematopoietic Stem Cell Transplantation or Other Cellular Therapy Recipients"	**Protocol:** Section 2.3	07/30/2018
1st paragraph, 3rd sentence: "Blood samples are donated by donors, CBUs and recipients who have registered, donated or received an allogeneic or autologous HSC transplant or other cellular therapy…"	**Protocol:** Section 1.2	07/30/2018
Updated Table of Contents to match body of the protocol.	**Protocol:** Page 2 Table of Contents	07/30/2018
Changed version # to 11.0 and version date to July 30, 2018	**Protocol:** Title page	07/30/2018
Added to end of paragraph: "You and your child will not be paid for taking part in the Research Sample Repository. It will not cost you anything for your child to participate in the repository. Research samples may be used for commercial projects and profit. If your child's sample is used for development of a commercial product, neither you nor your	**Recipient Consent Forms (Section V):** Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Consent**	01/24/2018

child will share in any profit."	**Forms (Section V):** Minor Marrow Toxic Injury Parent/Legal Guardian **Donor Consent Forms (Section V)** Minor Related Donor Parent/Legal Guardian;	
Added after 2nd paragraph: "To expand research, it is helpful for researchers to share information they get from studying research samples. They do this by putting the information into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to allow your child to take part in this study, some of your child's genetic and health information may be placed into a scientific database, such as "dbGAP" that is maintained by the National Institutes of Health. A researcher who wants to study the information must apply and be approved to use the database. The CIBMTR restricts the use of the data to studies related to transplant and cellular therapy. Data submitted to databases, such as dbGAP, may be used in additional research including genomic studies. Researchers with an approved study may be able to see and use your child's information pooled with information from many other individuals, but your child's name and other information that could directly identify your child will never be placed into a scientific database. Since your child's genetic data is unique to them, there is a chance that someone could trace it back to them. The risk is small, but may grow in the future if you or your child discloses genetic information linked to their identity. Researchers accessing your child's information will always have a duty to protect their privacy and to keep their information confidential. You may be concerned that someone could get access to your child's genetic information and that it could be misused. There are laws in place that make it illegal for an employer or health insurance company to discriminate against an individual based on their genetic information. Further, your child's privacy and the confidentiality of your child's data are very important to CIBMTR, and every effort will be made to protect them. You or your child will not directly receive any research results or data generated from your child's sample."	**Recipient Consent Forms (Section III):** Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Consent Forms (Section III):** Minor Marrow Toxic Injury Parent/Legal Guardian **Donor Consent Forms (Section III)** Minor Related Donor Parent/Legal Guardian;	01/24/2018

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Added 2nd paragraph: "The DNA testing may include "whole genome sequencing". Every cell in your child's body contains the genetic code for their DNA. Whole genome sequencing looks at the entire genome, or genetic code. All people have about 99.6% identical genomes. However, everyone is unique, and between any two people there could be about 24 million places where the "spelling" of the code is different. Associating these differences in spelling (gene variants) with differences in transplant or cellular therapy outcomes may help us to understand how these variants are related to disease and treatment success."	**Recipient Consent Forms (Section II):** Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Consent Forms (Section II):** Minor Marrow Toxic Injury Parent/Legal Guardian **Donor Consent Forms (Section II)** Minor Related Donor Parent/Legal Guardian;	01/24/2018
Added to end of paragraph: "You will not be paid for taking part in the Research Sample Repository. It will not cost you anything to participate in the repository. Research samples may be used for commercial projects and profit. If your sample is used for development of a commercial product, you will not share in any profit."	**Recipient Consent Forms (Section V):** Adult Allogeneic Recipient; **Marrow Toxic Injury Consent Forms (Section V):** Adult Marrow Toxic Injury; **Donor Consent Forms (Section V)** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement;	01/24/2018
Added after 2nd paragraph: "To expand research, it is helpful for researchers to share information they get from studying research samples. They do this by putting the information into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information may be placed into a scientific database, such as "dbGAP" that is maintained by the National Institutes of Health. A researcher who wants to study the information must apply and be approved to use the database. The CIBMTR restricts the use of the data to studies related to transplant and cellular therapy. Data submitted to databases, such as dbGAP, may be used in additional research including genomic studies. Researchers with an approved study may be able to see and use your information pooled with information from many other individuals, but your name and other information that could directly identify you will never be placed into a scientific database.	**Recipient Consent Forms (Section III):** Adult Allogeneic Recipient; **Marrow Toxic Injury Consent Forms (Section III):** Adult Marrow Toxic Injury; **Donor Consent Forms (Section III)** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement;	01/24/2018

Since your genetic data is unique to you, there is a chance that someone could trace it back to you. The risk is small, but may grow in the future if you disclose your genetic information linked to your identity. Researchers accessing your information will always have a duty to protect your privacy and to keep your information confidential. You may be concerned that someone could get access to your genetic information and that it could be misused. There are laws in place that make it illegal for an employer or health insurance company to discriminate against an individual based on their genetic information. Further, your privacy and the confidentiality of your data are very important to CIBMTR, and every effort will be made to protect them. You will not directly receive any research results or data generated from your sample."		
Added 2nd paragraph: "The DNA testing may include "whole genome sequencing". Every cell in your body contains the genetic code for your DNA. Whole genome sequencing looks at the entire genome, or genetic code. All people have about 99.6% identical genomes. However, everyone is unique, and between any two people there could be about 24 million places where the "spelling" of the code is different. Associating these differences in spelling (gene variants) with differences in transplant or cellular therapy outcomes may help us to understand how these variants are related to disease and treatment success."	**Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; **Marrow Toxic Injury Consent Forms (Section II):** Adult Marrow Toxic Injury; **Donor Consent Forms (Section II)** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement;	01/24/2018
Added 4th bullet: "Study the success of transplantation, cellular therapies, or supportive care in the management of marrow toxic injuries."	**Protocol:** Section 1.2	07/30/2017
Added 7th bullet: "Studies of the success of transplantation, cellular therapies or supportive care in the management of marrow toxic injuries."	**Protocol:** Section 8.1	07/30/2017
Changed study title to: Protocol for a Research Sample Repository for Allogeneic Hematopoietic Stem Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries	**Protocol:** Title page	07/30/2016
Changed NMDP's address	**Protocol:** Title page	07/30/2016
Added "cellular therapy" appropriately throughout the protocol	**Protocol:** throughout	07/30/2016
Changed references from "transplant center" to "treatment center" throughout the protocol	**Protocol:** throughout	07/30/2016
Paragraph 1, last sentence: "…outcomes of unrelated and related donor HCT and cellular therapies:"	**Protocol:** Section 8.1	07/30/2016
Paragraph 2, 1st sentence: "The CIBMTR is trying to learn more about what makes bone marrow, blood stem cell and	**Donor Consent Forms (Section I)**	07/30/2016

cord blood transplants and cellular therapies work well."	Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	
Paragraph 2, 2nd sentence: "Although the exact studies for which Research Repository samples may be used ~~is~~ are not known at this time…"	**Donor Consent Forms (Section I)** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section I):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	07/30/2016
Paragraph 2, 2nd bullet: "Determine and evaluate the factors that affect transplant and cellular therapy outcome;"	**Donor Consent Forms (Section I)** Adult Allogeneic Donor; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 2nd sentence: "The blood will be collected either just before your bone marrow, blood stem cell, or cellular therapy donation…"	**Donor Consent Forms (Section II)** Adult Allogeneic Donor; Minor Related Donor Parent/Legal Guardian;	07/30/2016
Paragraph 1, 2nd sentence: "The blood will be collected just before you start the conditioning regimen to prepare you for your transplant or cellular therapy."	**Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 2, 2nd sentence: "Your ~~transplant~~ treatment center and the CIBMTR have procedures in place to keep…	**Recipient Consent Forms (Section III):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Paragraph 3, 2nd sentence: "…who need a transplant or cellular therapy."	**Donor Consent Forms (Section III)** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section III):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 1st sentence: "Your ~~transplant~~ treatment center and the CIBMTR will not intentionally tell anyone that…"	**Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 2nd sentence: "Your ~~transplant~~ treatment center and the CIBMTR have procedures in place so that…"	**Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 2, last sentence: "This will not affect your relationship with your ~~transplant~~ treatment center or CIBMTR."	**Recipient Consent Forms (Section VI):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 2nd sentence: "…your bone marrow, blood stem cells, or cellular therapy donation will still be used ~~in a transplant~~ for the intended recipient…"	**Donor Consent Forms (Section VII)** Adult Allogeneic Donor; Minor Related Donor Parent/Legal Guardian;	07/30/2016
Paragraph 1, last sentence: "Please call your ~~transplant~~ treatment center coordinator immediately at…"	**Recipient Consent Forms (Section VIII):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 1st sentence: "…(~~Transplant~~ Treatment Center Medical Director) at…"	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 1st sentence: "…(~~Transplant~~ Treatment Center Coordinator) at…"	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian;	07/30/2016
Paragraph 1, 2nd sentence: "…is called a transplant or cellular therapy." Paragraph 1, 5th sentence: "This research project is about what makes these kinds of transplants or cellular therapies work."	**Assent Forms:** Related Donor Assent 7-11	07/30/2016

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Paragraph 2, last sentence: "…you can still do the transplant or cellular therapy donation for your brother or sister." Paragraph 4, last sentence: "…who are sick and need a transplant or cellular therapy."		
Paragraph 1, 2nd sentence: "…because you will be donating stem cells or a cellular therapy product to your brother or sister." Paragraph 1, last sentence: "The stem cells or cellular therapy product will be collected from…" Paragraph 2, 1st sentence: "…or cord blood transplants and cellular therapies work well." Paragraph 3, last sentence: "…you can still do the transplant or cellular therapy donation for your brother or sister." Paragraph 5, last sentence: "…who need a bone marrow or blood stem cell transplant or cellular therapy."	**Assent Forms:** Related Donor Assent 12-17	07/30/2016
Paragraph 1, 2nd sentence: "The research project is about what makes transplants and cellular therapies work." Paragraph 2, 3rd sentence: "Letting the CIBMTR use your blood is not about your transplant or cellular therapy." Paragraph 2, last sentence: "You will have a transplant or cellular therapy anyway." Paragraph 4, last sentence: "…and need a transplant or cellular therapy."	**Assent Forms:** Allo Recipient Assent 7-11	07/30/2016
Paragraph 1, last sentence: "…or cord blood transplant or cellular therapy." Paragraph 2, 1st sentence: "…or cord blood transplants and cellular therapies work well." Paragraph 2, 2nd sentence: "…who have had a transplant or cellular therapy to test different ways of matching…" Paragraph 3, last sentence: "You will have a transplant or cellular therapy for your disease…" Paragraph 5, last sentence: "…blood stem cell transplant or cellular therapy."	**Assent Forms:** Allo Recipient Assent 12-17	07/30/2016
Deleted the sentence: "~~The NMDP Registry lists more than 11 million volunteer donors, 204,000 cord blood units (CBU), and has facilitated over 66,000 unrelated HSC transplants~~."	**Protocol:** Section 1.1	07/30/2015
Replaced sentence as follows: "~~As of May 2014, there are over 116,000 unique blood samples in the NMDP Research Sample Repository.~~ Details of the research sample inventory are available at http://www.cibmtr.org/Samples/Inventory/Pages/index.aspx.	**Protocol:** Section 1.2	07/30/2015
Reworded last bullet point as follows: "In cases where the center has designated the NMDP IRB ~~on their center's FederalWide Assurance~~ as their IRB of record for the Research Repository protocol, and an IRB Authorization Agreement is in place, ~~for the Research Repository protocol,~~ the center does not need to obtain any additional IRB approval.	**Protocol:** Section 3	07/30/2015
Paragraph 3, last sentence: "Any research project may be	**Donor Consent Forms (Section**	02/24/2015

proposed for anonymous research, ~~examples include~~ such as: • ~~Studies that look at how certain genetic traits may affect transplant outcomes.~~ • ~~Studies that look at biological factors that may predict relapse after transplant.~~ • Studies that look for the presence of traits linked to other diseases, like diabetes."	**I):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section I):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	
Branding changes were applied to all consent and assent forms to remove references to NMDP (i.e., ~~NMDP/~~CIBMTR).	**Donor Consent Forms:** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms:** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms:** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian **Assent Forms:** Related Donor Assent 7-11; Related Donor Assent 12-17 Allo Recipient Assent 7-11; Allo Recipient Assent 12-17 Marrow Toxic Injury Assent 7-11; Marrow Toxic Injury Assent 12-17	7/30/14
Title of consent/assent forms: "~~National Marrow Donor Program® (NMDP) and Center for International Blood and Marrow Transplant Research® (CIBMTR®)~~ Contribution of a Blood Sample to the ~~National Marrow Donor Program's~~ Research Sample Repository"	**Donor Consent Forms:** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms:** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms:** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/14

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

	Assent Forms: Related Donor Assent 7-11; Related Donor Assent 12-17 Allo Recipient Assent 7-11; Allo Recipient Assent 12-17 Marrow Toxic Injury Assent 7-11; Marrow Toxic Injury Assent 12-17	
Paragraph 1, sentence 1: "The ~~National Marrow Donor Program (NMDP) and the~~ Center for International Blood and Marrow Transplant Research (CIBMTR), the research program of the National Marrow Donor Program (NMDP)/Be The Match, invites you to take part in the Research Sample Repository."	**Donor Consent Forms (Section I):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement **Recipient Consent Forms(Section I):** Adult Allogeneic Recipient **Marrow Toxic Injury Consent Forms (Section I):** Adult Marrow Toxic Injury	7/30/14
Paragraph 1, sentence 1: "The ~~National Marrow Donor Program (NMDP) and the~~ Center for International Blood and Marrow Transplant Research (CIBMTR), the research program of the National Marrow Donor Program (NMDP)/Be The Match, invites your child to take part in a Research Sample Repository."	**Donor Consent Forms (Section I):** Minor Related Donor Parent/Legal Guardian **Recipient Consent Forms (Section I):** Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section I):** Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/14
Deleted the sentence, "~~In these studies, there will be no way for the sample to be linked to you.~~"	**Donor Consent Forms (Section I):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient **Marrow Toxic Injury Consent Forms (Section I):** Adult Marrow Toxic Injury	7/30/14
Deleted the sentence, "~~In these studies, there will be no way for the sample to be linked to your child.~~"	**Donor Consent Forms (Section I):** Minor Related Donor Parent/Legal Guardian **Recipient Consent Forms (Section I):** Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section I):**	7/30/14

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

	Minor Marrow Toxic Injury Parent/Legal Guardian	
"All research studies using these blood samples must first be approved by a group of scientists within the ~~NMDP/~~CIBMTR as well as the Repository Oversight Committee. ~~NMDP~~ The proposed study will also be reviewed ~~the proposed study~~ to make sure the research is consistent with the types of studies described above."	**Donor Consent Forms (Section II):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian **Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section II):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/14
"Your donor center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Donor Consent Forms (Section IV):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement	7/30/14
"Your child's donor center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Donor Consent Forms (Section IV):** Minor Related Donor Parent/Legal Guardian	7/30/14
"Your treatment center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient **Marrow Toxic Injury Consent Forms (Section IV):** Adult Marrow Toxic Injury	7/30/14
"Your child's treatment center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Recipient Consent forms (Section IV):** Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section IV):** Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/14
"~~NMDP~~ Be The Match Donor Advocacy"	**Donor Consent Forms (Section IX):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian	7/30/14
"…with Be the Match® Patient and Health Professional Services…"	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient	7/30/14

	Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section VIII):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	
Removed ~~National Marrow Donor Program~~ from title page.	**Protocol:** Title Page	7/30/14
As of May ~~2013~~ 2014, there are over ~~100,000~~ 116,000 unique blood samples…	**Protocol:** Section 1.2	7/30/14
The NMDP Registry lists more than 11 million volunteer donors, ~~190,000~~ 204,000 cord blood units (CBU), and has facilitated over ~~55,000~~ 66,700 unrelated HSC transplants.	**Protocol:** Section 1.1	7/30/14
Addition: 8.6 Public Release of Data Generated on Samples……11	**Protocol:** Table of Contents on page 2	7/30/13
~~At the end of December 2008, the~~ The NMDP Registry ~~listed~~ lists more than ~~7.5~~ 11 million volunteer donors, ~~28,000~~ 190,000 cord blood units (CBU), and ~~had~~ has facilitated over ~~35,000~~ 55,000 unrelated HSC transplants.	**Protocol:** Section 1.1	7/30/13
First paragraph: "As of May ~~2012~~ 2013, there are over ~~90,000~~ 100,000 unique blood samples…"	**Protocol:** Section 1.2	7/30/13
First paragraph: "~~Twenty~~ Up to thirty milliliters (~~20~~ 30 mL) of blood…"	**Protocol:** Section 4.1.1	7/30/13
Second paragraph: "~~Samples from registered volunteer donors with rare tissue types will be collected at the donor's convenience any time after registration.~~ ~~Twenty~~ Up to thirty milliliters (~~20~~ 30 mL) of blood are collected from adult donors~~, except up to fifty (50 mL) may be collected from adult donors with rare tissue types~~."	**Protocol:** Section 4.1.1	7/30/13
First paragraph: "~~Ten~~ Up to thirty milliliters(~~10~~ 30 mL) of blood…"	**Protocol:** Section 4.1.2	7/30/13
Second paragraph: "For all donors, ~~10~~ up to thirty milliliters (~~10~~ 30 mL) of blood are collected."	**Protocol:** Section 4.1.2	7/30/13
First paragraph: "~~Twenty~~ Up to thirty milliliters (~~20~~ 30 mL) of blood are collected from an adult."	**Protocol:** Section 4.1.3	7/30/13
"Donor and recipient samples are stored as whole blood, peripheral blood mononuclear cells, cell lysates, extracted DNA, stabilized RNA, serum and plasma."	**Protocol:** Section 5.1	7/30/13
Added second paragraph: "In summary, all sample requests must meet the following release criteria prior to distribution of samples: • The proposed use of samples falls under the acceptable uses defined under section 8.1 for linked research or 8.2 for anonymous research per NMDP IRB Chair review. • The proposed study is deemed scientifically sound, feasible and high impact through acceptance by a CIBMTR Working Committee or • The planned use is for reference or quality control material only. • The proposed study is approved by the Repository Oversight Committee. • Consent status is confirmed in the CIBMTR database."	**Protocol:** Section 7.2	7/30/13

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

First paragraph: "Any research project may be proposed for anonymous research, examples include: • Studies that require self-identified race/ethnicity or other demographically defined healthy and/or disease controls. • Studies that need HLA specific immune stimulators for in vitro assays."	**Protocol:** Section 8.2	7/30/13
Added Section 8.6: 8,6 Public Release of Data Generated on Samples Research studies using Research Repository samples funded through the National Institutes of Health (NIH) are subject to the public data release policies of the NIH. The deposition of testing data from Research Repository samples into the NIH database of Genotypes and Phenotypes (dbGAP) will be permitted under the following conditions: • All sample data is stripped of identifying sequences, e.g. Y chromosome, mitochondrial DNA, or other unique sequences, dates and detailed demographic data prior to submission to dbGAP. • Access to sample data through dbGAP is limited to the controlled-access data process and use limited to research purposes defined in the consent.	**Protocol:** Section 8.6	7/30/13
Last paragraph: "~~In addition,~~ Investigators may conduct …" and "~~These studies are not limited to the types of studies listed above, or related to transplantation in general.~~ Any research project may be proposed for anonymous research, examples include: • Studies that look at how certain genetic traits may affect transplant outcomes. • Studies that look at biological factors that may predict relapse after transplant."	**Donor Consent Forms (Section I):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section I):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/13
First paragraph, last sentence: "…research studies related to transplant or other research as defined in this consent form."	**Donor Consent Forms (Section X):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm Enhancement; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section X):** Adult Allogeneic Recipient; Minor Allogeneic Recipient	7/30/13

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

	Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section IX):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	
First sentence: "…will be collected from a vein in your child's ~~arm~~ body."	**Donor Consent Forms (Section II):** Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section II):** Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section II):** Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/13
First sentence: "…where the blood is taken ~~from your child's arm~~."	**Donor Consent Forms (Section III):** Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section III):** Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section III):** Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/13
Paragraph 3, 1st sentence: "The blood sample will come from a~~n arm~~ vein in your body."	**Assent Forms:** Minor Related Donor (7-11)	7/30/13
Paragraph 3, 1st sentence: "…will be taken from a vein in your ~~arm~~ body." Paragraph 4, 1st sentence: "When the blood is taken ~~from your arm~~ you will…"	**Assent Forms:** Minor Related Donor (12-17)	7/30/13
Paragraph 3, 3rd sentence: "There is a chance the blood may have to come from a~~n arm~~ vein."	**Assent Forms:** Minor Allo Recipient (7-11)	7/30/13
Paragraph 3, 1st sentence: "…will be taken from your catheter or from a vein in your ~~arm~~ body." Paragraph 4, 2nd sentence: "If the blood is taken from a vein ~~in your arm~~, you will…"	**Assent Forms:** Minor Allo Recipient (12-17)	7/30/13
Paragraph 2,1st sentence: "…someone will take a small amount of blood from you~~r arm~~."	**Assent Forms:** Minor Marrow Toxic Injury (7-11)	7/30/13
Paragraph 3, 1st sentence: "…will be taken from your catheter or from a vein in your ~~arm~~ body." Paragraph 4, 2nd sentence: "If the blood is taken from a vein ~~in your arm~~, you will…"	**Assent Forms:** Minor Marrow Toxic Injury (12-17)	7/30/13

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Last sentence: "The NMDP/CIBMTR ~~will try hard to make sure~~ has procedures in place so that no one outside…"	**Donor Consent Forms (Section IV):** Adult Allogeneic Donor; Adult Registered Donor with Rare Tissue Type; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; **Marrow Toxic Injury Forms (Section IV):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/12
Paragraph 2: Second sentence, "…please contact a Patient Services Coordinator with ~~the NMDP Office of Patient Advocacy~~ Be the Match® Patient Services at…"	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Forms (Section VIII):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/12
Paragraph 1: Last sentence, "As of May ~~2009~~ 2012, there are over ~~46,000~~ 90,000 unique blood samples…"	**Protocol:** Section 1.2	7/30/12
Paragraph 2: Last sentence, "~~For all donors~~, ~~20~~ Twenty milliliters (20 mL) of blood are collected from adult donors except up to fifty (50 mL) may be collected from adult donors with rare tissue types."	**Protocol:** Section 4.1.1	7/30/12
Paragraph 1: Second sentence, "This includes, but is not limited to, any of the following…"	**Protocol:** Section 8.1	7/30/12
Added last bullet point, "Studies of global genetic diversity through genome-wide association studies or other techniques to evaluate the impact of other genetic factors on transplant outcome."	**Protocol:** Section 8.1	7/30/12
Discontinued the consent form "Adult Registered Donor with Rare Tissue Type." *(Although effective 7/30/2011, this change was not added to the Record of Revisions until 10/10/2011 due to an oversight.)*	**Donor Consent Form:** Adult Registered Donor with Rare Tissue Type	7/30/11
Paragraph 1: Last sentence, "You are being asked to participate because you have been exposed…"	**Assent Forms:** Minor Marrow Toxic Injury (12-17)	7/30/11
Paragraph 6: 2nd sentence, "Your doctors or your parents ~~cannot~~ will not make you give the blood sample…"	**Assent Forms:** Minor Related Donor (12-17); Minor Allogeneic Recipient (12-17); Minor Marrow Toxic Injury (12-17)	7/30/11
Paragraph 2: Last sentence, "No identifiable information	**Donor Consent Forms (Section**	7/30/11

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

about your child will be given to the researchers, nor will it be published or presented at scientific meetings."	**III):** Minor Related Donor Parent/Legal Guardian **Recipient Consent Forms (Section III):** Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Forms (Section III):** Minor Marrow Toxic Injury Parent/Legal Guardian	
Paragraph 2: Last sentence, "No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings."	**Donor Consent Forms (Section III):** Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm; **Recipient Consent Forms (Section III):** Adult Allogeneic Recipient; **Marrow Toxic Injury Forms (Section III):** Adult Marrow Toxic Injury;	7/30/11
Added second sentence to last paragraph: "Remember, you can change your mind at any time."	**Assent Forms:** Minor Allo Recipient (7 to 11); Minor Marrow Toxic Injury (7 to 11)	7/30/10
Added second sentence to last paragraph: "Remember, you can change your mind at any time and still give your special cells to your brother or sister."	**Assent Forms:** Minor Related Donor (7 to 11)	7/30/10
Second paragraph: "If you agree to be in this research project, ~~a nurse~~ someone will take a small ~~sample~~ amount of blood…"	**Assent Forms:** Minor Marrow Toxic Injury (7 to 11)	7/30/10
Second paragraph: "If you want to be in this research project, ~~your doctor~~ someone will take a small amount…"	**Assent Forms:** Minor Related Donor (7 to 11); Minor Allo Recipient (7 to 11)	7/30/10
Moved the first sentence of the first paragraph, "You are also being invited to be in a research project with the NMDP and CIBMTR." to be the fourth sentence.	**Assent Forms:** Minor Related Donor (7 to 11)	7/30/10
Paragraph 2: added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact a Patient Services Coordinator with the NMDP Office of Patient Advocacy at 1-888/999-6743 or patientinfo@nmdp.org."	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Forms (Section VIII):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Paragraph 1: Deleted the sentence "NMDP will pay for this treatment."	**Donor Consent Forms (Section VIII):** Minor Related Donor Parent/Legal Guardian	7/30/10

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Paragraph 2; added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact NMDP Donor Advocacy at 1-800/526-7809, extension 8710."	**Donor Consent Forms (Section IX):** Adult Related/Unrelated Donor; Minor Related Donor Parent/Legal Guardian; Adult Rare HLA Type Donor	7/30/10
Reworded first sentence as follows: "If you have questions, ~~or~~ concerns, or complaints about …"	**Donor Consent Forms (Section IX):** Adult Related/Unrelated Donor; Minor Related Donor Parent/Legal Guardian; Adult Rare HLA Type Donor **Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian **Marrow Toxic Injury Forms (Section VIII):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Added directive to transplant centers at the end of the first paragraph that "For related donors, transplant centers should include their standard local language that addresses injury for research participants."	**Donor Consent Forms (Section VIII):** Adult Related/Unrelated Donor	7/30/10
Added "for unrelated donors" at the end of the sentence "NMDP will pay for this treatment."	**Donor Consent Forms (Section VIII):** Adult Related/Unrelated Donor	7/30/10
Deleted the sentence: "Your child's blood sample will only be labeled with a number code."	**Donor Consent Forms (Section III):** Minor Related Donor Parent/Legal Guardian **Recipient Consent Forms (Section III):** Minor Allo Recipient Parent/Legal Guardian; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Deleted the sentence: "Your blood sample will only be labeled with a number code."	**Donor Consent Forms (Section III):** Adult Related/Unrelated Donor; Adult Rare HLA Type Donor; Adult Match Algorithm Donor; **Recipient Consent Forms (Section III):** Adult Allo Recipient; Adult Marrow Toxic Injury	7/30/10
Changed two tablespoons to three tablespoons.	**Donor Consent Forms (Section II):** Adult Rare HLA Type Donor	7/30/10
In second paragraph, changed "characterization" to "study".	**Donor Consent Forms (Section I):**	7/30/10

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

	Adult Match Algorithm Donor	
Clarified donor eligibility for rare allele and match algorithm enhancement activity	Protocol: Section 2.1	7/30/10
Changed volume to 50 mLs for donors with rare tissue types	Protocol: Section 4.1.4	7/30/10
Paragraph 2; added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact NMDP Donor Advocacy at 1-800/526-7809, extension 8710."	**Donor Consent Form (Section IX):** Adult Match Algorithm Donor	6/25/10
Reworded first sentence as follows: "If you have questions, ~~or~~ concerns, <u>or complaints</u> about …"	**Donor Consent Form (Section IX):** Adult Match Algorithm Donor	6/25/10
Sentence 1: Changed two tablespoons to three tablespoons.	**Donor Consent Form (Section III):** Adult Match Algorithm Donor	6/25/10
Changed NMDP Suite Number to 100	Protocol: Title page	7/30/09
Changed version to 5.1	Protocol: Title page	7/30/09
Changed year to 2009	Protocol: Title page	7/30/09
Updated number of volunteer donors and transplants	Protocol: Section 1.1	7/30/09
Updated number of unique samples in repository	Protocol: Section 1.2	7/30/09
Added "Transplant Center "	Protocol: Section 4.2	7/30/09
Added line to write in Donor ID on each page of donor consents	**Donor Consent Forms:** Adult Related/Unrelated Donor; Adult Match Algorithm Donor; Adult Rare HLA Type Donor	7/30/09
Added "or tissue" to Section I, second paragraph, second sentence.	**Donor Consent Forms:** Adult Match Algorithm Donor; Adult Rare HLA Type Donor	7/30/09
Reworded 3rd bullet in Section I as follows: "Study the distribution of tissue types in ~~different~~ populations; ~~e.g.~~, <u>for example,</u> ~~study tissue typing differences between different~~ <u>various</u> racial and ethnic populations<u>,</u> to help develop methods ~~that will~~ <u>to</u> improve tissue matching between donors and recipients."	**Donor Consent Forms:** Adult Related/Unrelated Donor; Adult Match Algorithm Donor; Adult Rare HLA Type Donor; Minor Related Donor Parent/Legal Guardian; **Recipient Consent Forms:** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian	7/30/09
Added "and Marrow Toxic Injuries" to title.	Protocol: Title page	7/30/08
Updated number of donors and HSC transplants through December 2007.	Protocol: Section 1.1	7/30/08
Updated number of unique blood samples in research repository through May 2008.	Protocol: Section 1.2	7/30/08
Added delinked research as fourth type of study where samples could be used	Protocol: Section 1.2	7/30/08
Included use of donors for tissue type characterization and enhancement of search algorithm.	Protocol: Section 2.1	7/30/08
Created eligibility of individuals with marrow toxic injury.	Protocol: Section 2.4	7/30/08
Created sample collection from individuals with marrow toxic injury.	Protocol: Section 4.1.3	7/30/08
Created sample collection from donors for tissue type characterization and algorithm enhancement.	Protocol: Section 4.1.4	7/30/08

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

Added "and plasma."	Protocol: Section 5.1	7/30/08
Clarified that studies for delinked research follow the same review/approval process as outlined in Section 7.2 of the Protocol	Protocol: Section 8.2	7/30/08
Created consent form for donors for tissue type characterization and algorithm enhancement.	Adult Registered Donor for Match Algorithm Enhancement Consent Form	7/30/08
Created consent form for adults with marrow toxic injury.	Adult Marrow Toxic Injury Research Sample Consent Form	7/30/08
Created permission form for minors with marrow toxic injury.	Minor Marrow Toxic Injury Parent/Legal Guardian Permission Form	7/30/08
Created minor assent form for minors with marrow toxic injury (7 to 11 years old).	Minor Marrow Toxic Injury Assent Form (7 to 11 years of age)	7/30/08
Created minor assent form for minors with marrow toxic injury (12 to 17 years old).	Minor Marrow Toxic Injury Assent Form (12 to 17 years of age)	7/30/08
Revised wording regarding anonymous research to "In addition, investigators may conduct resarch studies with stored blood samples that have had all identifiers removed. In these studies, there will be no way for the sample to be linked to you. NMDP/CIBMTR may allow investigators to use these anonymous samples for many other kinds of studies. Theses studies are not limited to the types of studies listed above, or related to transplantation in general."	Consent Forms Section I	7/30/08
Removed the sentence "Your blood sample will be used to look at ways to improve how patients are matched with their donors."	Consent Forms Section II	7/30/08
Added the sentence "Your blood sample will be frozen and stored indefinitely for possible use in future research studies."	Consent Forms Section II	7/30/08
Added that studies must be reviewed by a group of scientists "within NMDP/CIBMTR as well as the Repository Oversight Committee."	Consent Forms Section II	7/30/08
Removed mention that studies must be reviewed by the NMDP IRB and replaced it with "NMDP will also review the proposed study…"	Consent Forms Section II	7/30/08
Removed the sentence "An IRB is a group of people who protect the rights of research participants."	Consent Forms Section II	7/30/08
Clarified "No identifiable information about you" rather than just "Your name".	Consent Forms Section III	7/30/08
Added "Center for International Blood and Marrow Transplant Research (CIBMTR") to title.	Consent Forms	7/30/08
Changed "study" to "project."	Minor Assent Forms (7-11)	7/30/08
In last paragraph, changed "want to be in the research project" to "agree to give a small amount of blood for research."	Minor Assent Forms (7-11)	7/30/08
Throughout form replaced various mentions of "in this study" to various mentions of "give a blood sample for research."	Minor Assent Forms (12-17)	7/30/08
Removed "The NMDP would like the medical staff at your	Minor Related Donor Assent	7/30/08

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

donor center to take"	Form (12-17)	
Removed "The NMDP would like your doctor to have one of the medical staff at your hospital take"	Minor Allogeneic Recipient Assent Form (12-17)	7/30/08
Added "including testing of rare HLA types" to the third bulleted type of research studies	Protocol: Section 1.2	7/30/07
Clarified that NMDP IRB review is done "administratively" by the NMDP IRB Chair	Protocol: Section 8.0	7/30/07
Clarified review of delinked research studies, documenting NMDP IRB review is done "administratively" by the NMDP IRB Chair	Protocol: Section 8.2	7/30/07
Revisions to section 2.4 *Informed Consent*, to include mention of assent and refer to parental consent as "permission"	Protocol: Section 2.4	7/30/07
Revisions to Minor Assent section to state local IRBs are responsible for determination of method to document minor assent	Protocol: Section 2.4.1	7/30/07
Include caveat that minor must be "capable of providing assent" and confirm parent/legal guardian permission is sufficient if minor lacks capacity to provide assent	Protocol: Section 2.4.1	7/30/07
Included language addressing use of samples for anonymous research	Consent Forms Section I	7/30/07
Revised mention of Parent/Legal Guardian "consent" to "permission" in title and section statement section	Legal Guardian Consent Forms	7/30/07
Added full board name for IRB	Consent Forms Section II	7/30/07
To avoid repetitive language, revised section III stating the NMDP/CIBMTR will try hard to avoid a loss of confidentiality to read "NMDP/CIBMTR have procedures in place to keep your data private"	Consent Forms Section III	7/30/07
Replaced use of "quitting" in two instances to "change your mind" and "this" in the withdrawal language	Consent Forms Section IV	7/30/07
Updated site of Repository	Protocol: Section 1.2	6/11/07
Removed the option allowing centers to prepare site specific protocol	Protocol: Section 3	6/11/07
Updated section to include two sub-sections, one addressing collections for unrelated transplants and one addressing collections for related transplants	Protocol: Section 4.1	6/11/07
Included option for cell storage per "dried blood on filter paper"	Protocol: Section 5.1	6/11/07
Revised section to allow for NMDP IRB Chair administrative review for requests for samples – use of samples not considered "human research"	Protocol: Section 7.2	6/11/07
Added documentation that "Requestor will not receive any identifying information with the samples that could possibly be used to link the sample to the contributing individual."	Protocol: Section 8.5	6/11/07
Added documentation that "The link will never be released to an investigator."	Protocol: Section 10.1	6/11/07
Attachment removed – sites no longer allowed to prepare center specific protocol	Protocol: Attachment 1	6/11/07
Added CIBMTR to study invitation and referred to NMDP/CIBMTR throughout consent form	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor	6/11/07
For inclusion of related donors/recipients the types of studies	Consent Forms:	6/11/07

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

for which samples may be used revised to state "understanding tissue matching of related and unrelated donors and recipients	Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	
Revised statement regarding NMDP IRB approval to reflect administrative review process "The studies will also be reviewed by the NMDP IRB to make sure the research is consistent with the types of studies described above. An IRB is a group of people who protect the rights of research participants."	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	6/11/07
Revised language in Confidentiality section to state the NMDP/CIBMTR will not "intentionally" disclose subject's participation and will make every effort to maintain strict confidentiality	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	6/11/07
Prepared Parent/Legal Guardian consent form and Minor Assent forms for related donors requested to participate	New Consent Forms	6/11/07
Updated the number of unique blood samples included in the Repository to "over 38,000" as of May 2006	Protocol: Section 1.2	7/30/06
Clarified "parent or legal guardian" as the entity responsible for providing permission for minors to participate	Protocol: Section 2.4.1	7/30/06
Minor modifications clarifying the NMDP IRB Office's role in the IRB approval process for the Repository	Protocol: Section 3.1, 3.2	7/30/06
Updated the process by which requests for samples receive approval from the NMDP/CIBMTR	Protocol: Section 7.2	7/30/06
Revised wording regarding risks of collecting the blood sample from "may cause minor discomfort" to "will likely cause minor discomfort"	Recipient Consent Section III Legal Guardian Consent Section III Rare Tissue Type Donor Consent Section III	7/30/06
Revised wording regarding risks of collecting the blood sample from "you might feel some pain" to "will probably feel some pain"	Minor Assent Form (7-11) Minor Assent Form (12-17)	7/30/06
Revised wording regarding risk of identification of participant from "small risk that someone could find out which blood sample is yours" to small risk that an unauthorized person could find out which blood sample is yours"	Recipient Consent Form Section III Legal Guardian Consent Form Section III Rare Tissue Type Donor Consent Form Section III	7/30/06
Added sentence "It is up to you if you want to participate in the Research Repository"	Recipient Consent Form Section VI Legal Guardian Consent Form Section VI Rare Tissue Type Donor Consent Form Section VI	7/30/06
Corrected voluntary participation and withdrawal language to "you and your child"	Legal Guardian Consent Form Section VI	7/30/06
Removed the phrase "My signature below says that" from the subject's statement of consent	Recipient Consent Form Section X Legal Guardian Consent Form Section X Rare Tissue Type Donor Consent Form Section X	7/30/06
Discontinued use of donor consent combining language		7/30/06

regarding participation in Research Repository and Research Database		
Prepared separate consent form for donor participation in Research Sample Repository		7/30/06
New Principal Investigator	Protocol	7/30/05
Replaced Dennis Confer, M.D. with space to provide Donor Center Medical Director contact information	Donor Consent Section VIII	7/30/05
Corrected "You do not waive any liability rights for personal injury by signing this form" to "You do not waive any legal rights by signing this form."	Donor Consent Section VIII Donor w/ Rare Tissue Type Section VIII Recipient Consent Section VIII	7/30/05
Identification of the NMDP IRB as the group of people who monitor the use the data and protect the participant's rights.	Donor Consent Section II Recipient Consent Section II Donor w/ Rare Tissue Type Section II	7/30/05
Changed "Legal Guardian Consent" to "Parental /Legal Guardian Signature" and updated signature lines to "Parent/Legal Guardian"	Minor Assent Form (7 to 11) Minor Assent Form (12 to 17)	7/30/05
Prepared Parental/Legal Guardian consent form to be used with the minor assent forms		7/30/05
Protocol was revised, in accordance with the OHRP "Guidance on Research Involving Coded Private Information of Biological Specimens" to include a provision to obtain Cord Blood Unit (CBU specimens).	Protocol Sections: 2.2 (revised), 2.4 (revised), 2.4.2 (new), 4.2 (revised), and 5.1 (revised)	5/20/05
Volume of recipient blood sample reduced from 40mL to 20mL (three tablespoons to two tablespoons)	Protocol; Section 4.1, Attachment 1 Recipient Consent form; Section II	5/1/05
"Separation and…" removed from section 5.1 header	Protocol; Section 5.1	5/1/05
Removed language stating "When a recipient sample is received an attempt to made to isolate, collect and store peripheral blood mononuclear cells, granulocytes and serum."	Protocol; Section 5.1	5/1/05
Removed "on every recipient sample received at the Repository and" and replaced with "<u>and recipient</u>"	Protocol; Section 5.2	5/1/05
Updated samples in the repository to reflect 32,000 as of April 2004	Protocol Section 1.2, Paragraph 1, Line 7	7/30/04
Revised the volume of donor sample that will be drawn. The volume has been changed from 30mL to 20mL for donors.	Protocol Section 4.1 Paragraph 3, Line 4	7/30/04
Attachment 1 updated to include sample language from revised consent forms and the IRB recommendation to include a section to document the attestation of a counseling healthcare professional.	Protocol Attachment 1	7/30/04
Added the mention of cord blood transplants to the NMDP goal of research	Rare Tissue Type Consent form Section I, Paragraph 2, Line 2,3	7/30/04
Added the mention of cord blood transplants to the NMDP goal of research.	Rare Tissue Type Consent form	7/30/04
Removed "HLA" since the revised language refers to HLA type as "tissue type" only.	Rare Tissue Type Consent form Section II, Paragraph 2, Line 2, 3	7/30/04
Changed the sentence to read "The studies must also be approved by a group of people who *monitor the use of your*	Rare Tissue Type Consent form Section I, Bulleted Point 2	7/30/04

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

data and protect *your* rights."		
Changed the statement that the blood sample would not be used in any other research to the more correct statement that the sample "will be destroyed".	Rare Tissue Type Consent form Section VI, Paragraph 1, Line 2	7/30/04
Modified the format of the *Donor/Subject Statement of Consent*	Rare Tissue Type Consent form Section X	7/30/04
Consent form re-written at a more appropriate reading level	Recipient Consent form	7/30/04
Consent form re-written at a more appropriate reading level	Cord Blood Consent form	7/30/04
Consent form prepared to combine consent for donors to participate in both the Research Database and Research Repository studies.	Donor Consent form New consent form	7/30/04
Previous consent form for donor participation in Research Repository only, was removed from the study	Previous consent form for participation in Research Repository only, now replaced with combined consent form.	7/30/04
Added "registered" to the following sentence: … donors and recipients who have either "registered", donated or been transplanted…	Protocol Section 1.2, Paragraph 1, Line 5	1/28/04
Modified wording of "There are currently" to "As of July 2003 there are over 29,000 unique blood samples in the NMDP Research Sample Repository."	Protocol Section 1.2, Paragraph 1, Line 7	1/28/04
Added section to address the types of studies that NMDP allows samples to be used without obtaining additional consent from the participants	Protocol Section 1.2, Paragraph 3	1/28/04
Paragraph added indicating registered donors with rare tissue types will be included as eligible participants in the Research Repository.	Protocol Section 2.1, Paragraph 2	1/28/04
Collection time for registered donors with rare tissue type added.	Protocol Section 4.1, Paragraph 3, Lines 2-4	1/28/04
Prepared an additional Research Repository consent form to be used by registered donors with rare tissue types	Consent form titled: *Contribution of a Blood Sample to the National Marrow Donor Program's Research Sample Repository: Registered Donor with Rare Tissue Type Consent Form*	1/28/04

Formatting changes Number of transplants updated Number of stored samples updated	Protocol Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject	10/1/03
Section added addressing justification of Minor Assent	Protocol Section 2	10/1/03
Section added outlining IRB approval process for centers contributing a research sample	Protocol Section 3	10/1/03
Revision to donor samples used for cell transformation	Protocol Section 5.2	10/1/03
Section added to address participant withdrawal from the Research Repository	Protocol Section 9	10/1/03
Attachment added defining minimum requirements set forth	Protocol Attachment 1	10/1/03

RECORD OF REVISIONS:

Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries

(IRB-1991-0002)

by the NMDP IRB for centers writing their own protocols and consent forms		
Reference to sample being separated into cells and plasma removed	Sections I, II Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Phrase "ethnic" replaced with "racial and ethnic"	Sections I, II Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Section added to address alternatives to participation	Section VII Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
The "Authorization to Use and Disclose Health Information for Research Purposes" removed	Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Statement "The NMDP will pay for this treatment." removed from consent form for recipients	Sections VIII Recipient/Subject Consent	10/1/03
"Unrelated donors" changed to "Cord Blood Units" or "CBUs"	Cord Blood Donor/Subject Consent	10/1/03
Minor Assent for ages 7 to 11 approved		10/1/03